In regards to your request to have HHS stop DME suppliers from contacting beneficiaries when it is not solicited, CMS asks for more information on this matter so that appropriate action can be taken.

Section 1834(a)(17)(A) of the Social Security Act (the Act) prohibits suppliers of DME from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of a covered item, except in three specific situations: (i) the beneficiary has given written permission to the supplier to make contact by telephone regarding the furnishing of the covered item; (ii) the supplier has furnished a covered item to the beneficiary and the supplier is contacting the individual only regarding the furnishing of such covered item; or (iii) if the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the beneficiary during the 15-month period preceding the date on which the supplier makes such contact.

Under Section 1834(a)(17)(B) of the Act, if a supplier knowingly contacts a beneficiary in violation of Section 1834(a)(17)(A) of the Act, no payment may be made under Part B for any item subsequently furnished to the beneficiary by the supplier. Accordingly, such claims for payment are false and violators are potentially subject to criminal, civil, and administrative penalties, including exclusion from Federal health care programs.[2] In order to address these incidents, please either provide the information on the DME suppliers making the unsolicited telephone calls back to me in writing or contact 1-800 MEDICARE and report all occurrences so that CMS and/or HHS OIG can investigate and take appropriate action.

Finally, regarding your concern about the efficacy of "unbranded" DTS, Medicare coverage and payment is not allowed for DTS or other products that do not meet safety and efficacy requirements established by the Food and Drug Administration (FDA). Under Medicare, suppliers of DME must be accredited and meet quality standards, including the requirement to only furnish products that meet applicable FDA regulations and medical device effectiveness and safety standards. Nonetheless, we suggest that you provide detailed information about your concerns with specific products directly to the FDA for their consideration. In addition, we are not certain what "unbranded" diabetes test strips refers to, as generic test strip products were taken off the market in the early 1990s. With regard to brands of test strips furnished via mail-order to Medicare beneficiaries, the HHS OIG analyzed supplier documentation of brands of test strips furnished to beneficiaries for the 3-month period of April to June 2013 leading up to implementation of the national mail-order program for diabetes test strips on July 1, 2013.[3] They also analyzed supplier documentation for the brands of test strips furnished to beneficiaries for the 3-month period from July through September 2013.[4] These studies showed little change in the top 10 brands furnished to beneficiaries before and after implementation of the mail order program. We suggest that you provide detailed information about your concerns regarding the efficacy of specific DTS products directly to the FDA for their consideration.

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[2] http://oig.hhs.gov/fraud/docs/alertsandbulletins/fraudalert_telemarketing.pdf
[3] http://oig.hhs.gov/oei/reports/oei-04-13-00681.pdf
[4] http://oig.hhs.gov/oei/reports/oei-04-13-00680.pdf